UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ROSEMARY WILHITE, et al., Plaintiffs, vs. HOWMEDICA OSTEONICS CORP., et al., Defendants.	)	CASE NO. 5:10cv2471 JUDGE SARA LIOI **MEMORANDUM OPINION AND ORDER** [Resolving Doc. 19]

This matter comes before the Court on the motion of Defendants, Howmedica Osteonics Corp., Howmedica, Inc., Stryker Corp., Stryker Sales Corp., and Stryker Orthopaedics (collectively "Defendants") for summary judgment. (Doc. 19.) The matter is fully briefed and is ripe for this Court's disposition.

I. Background

Defendants are several corporations[1] that had some part in the production of the Trident System, a prosthetic hip device. Plaintiffs are Jerry and Rosemary Wilhite (collectively "Plaintiffs"). Rosemary Wilhite ("Mrs. Wilhite") received a hip replacement in September 2004, which Defendants have since determined involved the implantation of the Trident System[2] ("Trident" or "Trident System"), a fact that Plaintiffs do not dispute. After the hip replacement procedure, Plaintiffs assert that Mrs. Wilhite was "seriously and permanently injured when [the] prosthetic device malfunctioned and broke." Compl. at ¶ 15. During a second surgery, it was determined that "the prosthetic hip device and/or its components malfunctioned and/or were

[1] Defendants assert in their motion for summary judgment that neither Stryker Orthopaedics nor Howmedica, Inc., is a legally viable entity, but that the motion has been filed on their behalf as well. Neither party has otherwise made an issue of the named Defendants' involvement in the production of the Trident System.

[2] Throughout their brief and exhibits, Defendants have meticulously included the trademark designation when referring to the Trident System. The Court acknowledges that designation, but has omitted it from this Opinion.

defective, causing severe injuries to [Mrs. Wilhite]." *Id.* Plaintiffs have brought this action against Defendants to recover damages for Mrs. Wilhite's injuries and to pursue a loss of consortium claim for Mr. Wilhite. Defendants have moved for summary judgment on the issue of the federal pre-emption of Plaintiffs' state law claims.

The Trident is a hip replacement system "composed of the following components: a Trident Alumina Insert, Trident Alumina Femoral Head, Trident Acetabular Shell, and a femoral stem component." (Aff. of M. Many, Doc. 19-1 at ¶ 4.) The parties have determined that the Trident was used in this instance because an identifying label is affixed to each component of the Trident System, which is then removed from the components and affixed to a patient's medical chart at the time of implantation. That procedure was followed in this instance, and each of the labels in Mrs. Wilhite's medical chart indicates that the Trident System was used.

The parties do not dispute the fact that the Trident is a Class III medical device under the provisions of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c *et seq.*, to the federal Food, Drug and Cosmetics Act ("FDCA"). The MDA places medical devices into one of three categories or classes based upon the risks that they pose to patients. The parties do not dispute that the class into which the Trident is put is Class III, which includes any device that cannot be classified as Classes I or II, and "is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C). A Class III device is therefore "subject [...] to premarket approval to provide reasonable assurance of its safety and effectiveness." *Id.* The parties further do not dispute that, because Trident is a Class III device, it underwent the premarket approval process.

The premarket approval process ("PMA") is a rigorous process by which these Class III devices are approved for entrance into the market. The Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-20 (2008), describes Class III devices and the PMA process as follows:

> The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators, FDA, Device Advice: Device Classes, *supra*. In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii).
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> Premarket approval is a "rigorous" process. *Lohr v. Medtronic, Inc.*, 518 U.S. 470, 477 (1996). A manufacturer must submit what is typically a multivolume application. FDA, Device Advice-Premarket Approval (PMA) 18, http:// www. fda.gov/cdrh/devadvice/pma/printer.html. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. § 360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a) (2007), and may request additional data from the manufacturer, § 360e(c)(1)(G).
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> The FDA spends an average of 1,200 hours reviewing each application [*Lohr*, 518 U.S. at 477] and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness," § 360e(d). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C). It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives. It approved, for example, under its Humanitarian Device Exemption procedures, a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent. FDA, Center for Devices and Radiological Health, Debakey VAD Child

> Left Ventricular Assist System-H030003, Summary of Safety and Probable Benefit 20 (2004), http://www.fda.gov/cdrh/pdf3/H030003 b.pdf.
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> The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A).
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> After completing its review, the FDA may grant or deny premarket approval. § 360e(d). It may also condition approval on adherence to performance standards, 21 CFR § 861.1(b)(3), restrictions upon sale or distribution, or compliance with other requirements, § 814.82. The agency is also free to impose device-specific restrictions by regulation. § 360j(e)(1).
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> If the FDA is unable to approve a new device in its proposed form, it may send an "approvable letter" indicating that the device could be approved if the applicant submitted specified information or agreed to certain conditions or restrictions. 21 CFR § 814.44(e). Alternatively, the agency may send a "not approvable" letter, listing the grounds that justify denial and, where practical, measures that the applicant could undertake to make the device approvable. § 814.44(f).
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> Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. § 360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. § 360e(d)(6); 21 CFR § 814.39(c).
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> After premarket approval, the devices are subject to reporting requirements. § 360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, § 803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. § 360e(e)(1); see also § 360h(e) (recall authority).

Riegel, 552 U.S. at 317-20.

Separate from the PMA process is the provision under the FDCA that allows devices sold prior to the effective date of the MDA to be grandfathered into the system, and

allows devices that are substantially similar to the grandfathered devices to avoid the PMA process. While the grandfathered devices remain on the market "until the FDA promulgates [...] a regulation requiring premarket approval [] (§§ 360c(f)(1), 360e(b)(1))[,]" *Riegel*, 552 U.S. at 317, there is a separate procedure for devices that are equivalent to those that are grandfathered. In order to limit the competitive advantage of those pre-existing devices,

> [a] new device need not undergo premarket approval if the FDA finds it is "substantially equivalent" to another device exempt from premarket approval. § 360c(f)(1)(A). The agency's review of devices for substantial equivalence is known as the § 510(k) process, named after the statutory provision describing the review. Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices. P. Hutt, R. Merrill, & L. Grossman, Food and Drug Law 992 (3d ed.2007).

Id. The Court mentions the § 510(k) process for the purpose of contrasting the rigors of review under each of the standards, namely § 510(k) and § 360c. None of the parties to this action proposes that the Trident was subject to the § 510(k) process.

II. Legal standard

Rule 56 of the Federal Rules of Civil Procedure, addressing Summary Judgment, provides in relevant part as follows:

> **(a) Motion for Summary Judgment or Partial Summary Judgment.** A party may move for summary judgment, identifying each claim or defense--or the part of each claim or defense--on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.
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> **(c) Procedures.**
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> **(1)** ***Supporting Factual Positions.*** A party asserting that a fact cannot be or is genuinely disputed must support the assertion by:

> **(A)** citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or
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> **(B)** showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.

A movant is not required to file affidavits or other similar materials negating a claim on which its opponent bears the burden of proof, so long as the movant relies upon the absence of the essential element in the pleadings, depositions, answers to interrogatories, and admissions on file. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986).

In reviewing summary judgment motions, this Court must view the evidence in a light most favorable to the non-moving party to determine whether a genuine issue of material fact exists. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970); *White v. Turfway Park Racing Ass'n.*, 909 F.2d 941, 943-44 (6th Cir. 1990). A fact is "material" only if its resolution will affect the outcome of the lawsuit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Determination of whether a factual issue is "genuine" requires consideration of the applicable evidentiary standards. Thus, in most civil cases the Court must decide "whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict[.]" *Id*. at 252.

Summary judgment is appropriate whenever the non-moving party fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will bear the burden of proof at trial. *Celotex*, 477 U.S. at 322. Moreover, "the trial court no longer has a duty to search the entire record to establish that it is bereft of a genuine issue of material fact." *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 (6th Cir. 1989)

(*citing Frito-Lay, Inc. v. Willoughby*, 863 F.2d 1029, 1034 (D.C. Cir. 1988)). The non-moving party is under an affirmative duty to point out specific facts in the record as it has been established which create a genuine issue of material fact. *Fulson v. Columbus*, 801 F. Supp. 1, 4 (S.D. Ohio 1992). The non-movant must show more than a scintilla of evidence to overcome summary judgment; it is not enough for the non-moving party to show that there is some metaphysical doubt as to material facts. *Id*.

As set forth above, the issue before the Court is whether the claims Plaintiffs have brought are pre-empted by federal law. The federal pre-emption doctrine is based upon the Supremacy Clause of the United States Constitution. *State Farm Bank v. Reardon*, 539 F.3d 336, 341 (6th Cir. 2008). The Supremacy Clause provides that the Constitution, federal law, and all treaties "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Federal law may pre-empt state law either expressly or impliedly. *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1982). Express pre-emption exists where either a federal statute or regulation contains explicit language indicating that a specific type of state law is pre-empted. *See id*. at 153.

Implied pre-emption is further divided into two categories: "field pre-emption" and "conflict pre-emption." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). Field pre-emption exists "where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it[.]" *Id.* (quotation and citation omitted). Conflict pre-emption occurs "where compliance with both federal and state regulations is a physical impossibility," or "where state law stands as an

obstacle to the accomplishment and execution of the full purposes and objectives of Congress[.]" *Id.* (internal citations omitted).

Any pre-emption analysis is guided by two important considerations. First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks and alteration omitted). Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated … in a field which the States have traditionally occupied,' … we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Lohr*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

III. Analysis

In their motion for summary judgment, Defendants rely upon *Riegel* for the contention that all of Plaintiffs' claims are pre-empted by the FDCA because the state laws under which those claims are brought would impose different or more restrictive requirements on the manufacturer of the Trident System than would the FDA's regulations. Under 21 U.S.C. § 360k(a),

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
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> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The *Riegel* decision involved an action brought by a patient[3] who had suffered injury when a balloon catheter that was being used to dilate his coronary artery ruptured. *Riegel*, 552 U.S. at 320. The patient brought an action against the manufacturer claiming that the catheter "was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused [him] to suffer severe and permanent injuries." *Id.* Included were several common law claims such as strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the catheter. *Id.* The district court had found that these common law claims were pre-empted under the MDA, as was a common law claim for negligent manufacturing insofar as it did not allege a violation of federal law. *Id.* at 321. The appellate court affirmed. *Id.*

Having confirmed that the catheter in question was a Class III device that had undergone the PMA process, the Supreme Court noted that it was faced with two questions regarding the issue of pre-emption. First, it had to "determine whether the Federal Government ha[d] established requirements applicable to [the manufacturer's] catheter." *Id.* If it had, the Court would then have to resolve the question of "whether [the patient's] common-law claims [were] based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness."[4] *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)). In clarifying this "different from or in addition to" standard, the Court stated that those claims that are claims "premised on a violation of FDA regulations" are "parallel" claims, and do not impose requirements that are different from or in addition to federal

[3] The action in *Riegel* was originally brought by the patient and his wife. During the course of the litigation, the patient passed away and his widow and his estate continued to pursue the claims. *Riegel*, 552 U.S. at 321 n. 3. This history is not integral to the Court's discussion, and the Court will simply refer to the plaintiffs in the matter as "the patient."

[4] The following The Supreme Court also attempted to clarify what it means for a state requirement to be "different from or in addition to" an MDA requirement. The Court said that state claims "premised on a violation of FDA regulations" are "parallel" claims, and do not impose requirements that are different from or in addition to federal requirements. [*Riegel*, 552 U.S. at 330.] Therefore, § 360k(a) of the MDA does not pre-empt these parallel claims.

requirements. *Id.* at 330 (citing *Lohr*, 518 U.S. at 495). In such instances, § 360k(a) of the MDA does not pre-empt parallel state claims. *See also White v. Stryker Corp.*, --- F. Supp.2d ---, No. 3:10cv544, 2011 WL 1131496 at *4 (W.D. Ky. 2011).

In answer to the first question of whether the federal government established requirements for the catheter in *Riegel*, the Court found that the PMA process, which the catheter had undergone, does place requirements on the products. *Riegel*, 552 U.S. at 323. Those requirements are at their core ones of safety and effectiveness: "[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* The Court then held that, in the case before it, state law causes of action imposed requirements on the manufacturer that were different from or in addition to those imposed by the FDA. *Id.* at 324-25. In sum, the Court held that, to the extent that a plaintiff alleges that a defendant manufacturer is liable under state common law theories of negligence, strict liability, or breach of warranty even though the manufacturer complied with the FDA requirements, those claims are pre-empted by federal law.

The cases addressing this issue post-*Riegel* are in line with the proposition that, if a plaintiff alleges that harm he has suffered as a result of a Class III device's mislabeling or malfunctioning even though the product had adhered to the PMA standards established for it and had otherwise complied with federal requirements, those claims are pre-empted by federal law; certain state law or common law claims that allege harm resulting from a manufacturer's failure to adhere to the federal requirements may not be pre-empted. *See, e.g., Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 532 (S.D. Tex. 2009), *aff'd* 631 F.3d 777 (5th Cir. 2011) (the plaintiff's assertions that some of his claims arose out of violations of FDA requirements did not overcome

the fact that the complaint "[did] not cite a single FDA requirement violated by [the defendant][.]"); *Horowitz v. Stryker*, 613 F. Supp. 2d 271, 280 (E.D. NY 2009) (generalized and vague references to Defendants' purported violations of FDA regulations neither specifically implicated the device used for the plaintiff nor connected alleged violations to her injuries); *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006) (claims made based on the adequacy of language in labels that have been approved by the FDA are pre-empted); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298 (claims regarding Trident System pre-empted as not being parallel to federal requirements).

As Defendants note, many courts—both district and circuit—have concluded that claims regarding the Trident System are pre-empted by federal law, even in cases in which the plaintiffs cited the federal regulations and standards they believed Trident had violated, either in its labeling or its functioning. The Court has already cited several of these cases. *See Funk v. Stryker*, 673 F. Supp. 2d 522; *Horowitz v. Stryker*, 613 F. Supp. 2d 271; *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298. In this matter, however, Plaintiffs made no mention of FDA regulations in their complaint. Each of their claims was a claim strictly under the common law or state statute.

In their very brief response in opposition to the motion for summary judgment, Plaintiffs counter by citing three cases in which a court found that a plaintiff's claims were not pre-empted, namely *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp.2d 830 (S.D. Ind. 2009), *Warren v. Howmedica Osteonics Corp.*, No. 4:10CV1346, 2010 WL 5093097 (E.D. Mo. 2010), and *Prudhel v. Endologix, Inc.*, No. CIV S-09-0661, 2009 WL 2045559 (E.D. Cal. 2009). It is apparently Plaintiffs' argument that, though Defendants cited a number of cases in which the

claims were pre-empted, they did not cite these cases in which the claims were found not to be pre-empted, and the fact that they did not should be persuasive to this Court.

In actuality, Defendants did cite both the *Hofts* and *Warren* cases in their motion at page 7 and in their reply brief at footnote 2, bringing to the Court's attention the fact that the courts issuing those opinions were in a small minority of courts that denied motions to dismiss claims relating to the Trident System. Furthermore, as Defendants note in their reply brief at page 3, there are a number of cases that rejected the pleading standard set forth in *Hofts* and *Warren* as being overly lax, including one case out of the Northern District of Ohio. *See* Reply at 3, citing, among others, *Anthony v. Stryker Corp.*, 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio 2010). The Court finds persuasive Defendants' argument that, even under the lax pleading standard of *Hofts*, Plaintiffs' claims cannot survive. In *Hofts* and *Warren*, the plaintiffs cited specific FDA regulations or PMA standards that the defendants allegedly violated. *See Hofts*, 597 F. Supp.2d at 836; *Warren*, 2010 WL 5093097 at *2; *Prudhel*, 2009 WL 2045559 at *8.

As to the other case cited by Plaintiffs, namely *Prudhel*, Defendants point out in their reply brief that the medical device at issue was not a Trident System. Moreover, although *Prudhel* takes a different approach than some courts regarding the interpretation of parallel claims and finds that a strict liability claim may be considered a parallel claim even when it requires that elements in addition to the violation of a federal regulation must be proven, the most basic requirement that the court finds the plaintiff to have satisfied is the pleading of a federal violation. *Prudhel*, 2009 WL 2045559 at *8. The court held that the plaintiff had adequately pled a state law strict liability claim that was not pre-empted when he alleged that "the [defendant's] manufacturing was not in compliance with the requirements imposed by 21 C.F.R. § 820, resulting in a defect." *Id.* Each of the remaining allegations in the plaintiff's

complaint was pre-empted because none of them clearly established a federal violation or made more than a vague assertion of a federal violation. *Id.*

In contrast with all three of these cases, Plaintiff's complaint makes no assertion of federal violations at all. To imply that the complaint in the instant matter is saved by any of the above named cases is almost disingenuous when the allegations in the respective complaints are so clearly dissimilar. Furthermore, merely finding cases that survived the pre-emption analysis does not make Plaintiffs' argument. Plaintiffs' complaint shares nothing in common with the pleadings in those cases.

In their short response, Plaintiffs make two more arguments. First, they seem to argue that it is not fair to cut off their only avenue for recourse from the harm Defendants' alleged wrongdoing caused them. (Doc. 20 at 2.) This is a difficulty that has given other courts pause. *See Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744, 755 (M.D. Pa. 1992). However, as the Supreme Court stated in *Riegel*,

> It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available—the text of the statute—suggests that the solicitude for those injured by FDA-approved devices […] was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.

Riegel, 522 U.S. at 326. Congress has constructed the statutory scheme, and the Supreme Court has interpreted it as pre-empting the complaint Plaintiffs have filed in this matter.

Plaintiffs' final argument is that the additional components used for the surgical implantation of the Trident System were not actually part of the "system," and therefore any claims regarding those components are not pre-empted. Plaintiffs identify the following components as those of the Trident System: the alumina insert, the alumina femoral head, the acetabular shell and the femoral stem component. The additional components they identify as

potentially being outside of the Trident System and therefore not subject to pre-emption are the bone screw, taper head, and adapter sleeve. They cite no case law in support of their argument.

Defendants respond that Plaintiffs never pled a claim based on the failure of the component parts, and relied instead upon the alleged failure of the Trident System itself, citing Plaintiffs' allegation that the "'prosthetic device malfunctioned and broke.'" (Doc. 22 at 3 (quoting complaint at ¶ 15) (emphasis omitted).) Defendants are correct: Plaintiffs clearly assert in their complaint the failure of the "prosthetic hip device and/or *its* component parts." (Complaint, Doc. 1-2 at ¶¶ 20, 31, 42) (emphasis added). Plaintiffs clearly used the possessive adjective emphasized above to identify the Trident System's component parts in their complaint. They cannot amend their complaint by means of the argument in their opposition to Defendants' motion, and cannot now argue that the "component parts" to which they referred in their complaint were parts outside of the FDA-approved Trident System by means of which they now hope to save their claims from pre-emption.

In their reply brief, Defendants cited numerous cases in support of the proposition that components of medical devices will not be separately considered when the device as a whole underwent the PMA process and received approval. Some of Defendants' citations involved the Trident System specifically. *See, e.g., Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648 (S.D. Tex. 2010); *Delaney v. Stryker Orthopaedics*, No. 08-03210, 2009 U.S. Dist. LEXIS 16865 (D.N.J. 2009). The Court finds that the case law is clear on this subject and is unpersuaded by Plaintiffs' attempt to imply that they intended to include other component parts unrelated to the Trident System in their complaint. Rather than engage in this discussion, however, the Court once again notes that Plaintiffs have failed to allege any violation by Defendants of the FDA regulations or PMA standards relating to the Trident System or any component parts Plaintiffs may attempt at

this point to identify. Without any such allegations, the Court finds that Plaintiffs have raised purely state law or common law claims that impose standards different from or in addition to those imposed by the FDA, and those claims are therefore pre-empted.

IV. Conclusion

For the reasons set forth herein, all of the claims in Plaintiffs' complaint are pre-empted by federal law. Defendants' motion for summary judgment is therefore GRANTED.

IT IS SO ORDERED.

Dated: June 20, 2011

HONORABLE SARA LIOI
UNITED STATES DISTRICT JUDGE